

To: CDRH All-Hands

From: Director, Center for Devices and Radiological health

Date: July 29, 2005

Subject: CDRH Third Quarter Strategic Plan Program Review

Below is a summary of our third quarter status report on the 20 projects that are part of the Center FY 05 strategic plan. I wanted to pass this information on to you because I think it's important to keep everyone abreast of where we stand.

Center management meets quarterly to discuss the status of these project management plans. These plans describe the project and its relevance to the Center, specifies milestones and explains project costs. We conduct these quarterly project reviews to assess where we are on the projects, whether we're accomplishing what was planned on schedule, and what problems may lie ahead. The third quarter review summarized below took place during a meeting of senior managers on June 8. The last one for this year is scheduled for September 29.

As you can see, these project management plans (like organizational scorecards) involve every Office, so everyone has a stake in their success. I hope that reading the summaries will stimulate your interest for more information about the various projects. If that happens, don't hesitate to contact your Office Director, or OCD's Nancy Braier at 301-827-7967.

Thank you for your continuing support of the Center and its mission.

Daniel G. Schultz, M.D.

## **CENTER-WIDE ISSUES**

### **1. Planning for FY 06**

Senior staff agreed to schedule a two-day go-away on August 23-24. Participants will include OCD staff and Office Directors. The go-away will address questions like what the Center's FY 06 priorities should be.

### **2. Project Management Plans**

- Progress on project management plans was reported for the third quarter, using a standard electronic reporting template including: the original project management plan milestones, progress report for this quarter, what is expected for the next quarter; and adjustments. Offices should report fourth quarter progress by 9/23.

## **THIRD QUARTER UPDATES (by Office)**

### **OCD**

#### **1. Medical Device Fellowship Program**

- MDFP personnel drafted standard operating procedures (SOPs) and are finalizing SOPs by incorporating Office comments.
- MDFP allocated FY 05 resources and met Office priorities.
- Offices need to clarify their FY 06 MDFP priorities.

#### **2. Organizational Scorecards**

- The second quarter scorecard report was finalized and posted on the strategic planning sites of Centernet and Internet.
- Second quarter Office scorecard reports are available to the Offices through eRoom.
- Offices should provide third quarter scorecard reports to OCD by 7/29.

#### **3. Guidance development**

- 46% (19 of 41) high priority new guidances had been approved by CDRH and sent for FDA clearance. The project is on track to meet the end of year target of 70% (29 of 41).
- Offices should send their priorities on updating (or withdrawing) existing guidances to Linda Kahan and the Regulations Staff.

### **OC**

#### **4. Contractor for design, development, and implementation of OC-wide tracking and workflow, integrated with ODE**

- OC has added funds to get the contract started. The contractor will develop the concept of operations for the tracking system.
- OC needs to clarify design and implementation timeline and costs for FY 06.

#### **5. Registration and listing requirements development**

- OC awarded a contract for \$200K on schedule
- OC needs to clarify the scope and cost-benefit of the CDRH project, within the overall requirements of the FDA registration and listing system.

## **ODE**

### **6. E-Consult Pilot**

- Tony Watson is the new leader for this project. He is working with the project team addressing IM Steering Committee recommendations.
- ODE needs to update the concept of operations for this project, and clarify what can be accomplished with a revised concept of operations and current funding.

### **7. Scanning ODE Documents**

- The 513(g) s backlog was scanned. CDRH awarded a contract that will reduce PMA scanning time to two days.
- On June 6, the software to support expanded electronic review became available.
- Plans are to make the software widely available to reviewers by October.

### **8. Division Tracking System upgrades needed to meet MDUFMA time-frames**

- DTS task order was issued in February, and upgrades will take place in a series of “releases.”
- Upgrading the tracking system for modular PMAs may require additional funding.

### **9. Pre-market database and tracking system improvements**

- ODE needs to identify a project lead.
- ODE needs to develop and get agreement on a concept of operations.

## **OCER**

### **10. Radiological health strategic plan implementation**

- COMPLETED - Implementation took place on schedule.

### **11. New employee orientation program**

- On Target

### **12. Core competencies**

- Senior staff approved supervisory core competencies, which are included in FY 05 scorecards.
- OCER needs to brief the Executive Committee on core competencies for staff.

### **13. Continuing Science Education Program**

- SLEP Program is On Target
- OCER needs to evaluate the Georgetown/VA Tech science leadership program for continuation beyond the current term.

## **OIVD**

### **14. Turbo-510(k) development**

- Installation of “e-reviewer” software began in March and is mostly on schedule. There may be additional software and development costs next year.
- Five firms have participated in the pilot test so far. OIVD hopes to have 4 more.
- OIVD needs to clarify what can be accomplished with current funding.

## **OSB**

### **15. Conditions of Approval**

- On Target
- The official transfer of this function occurred on schedule January 1.
- CDRH sent guidance to FDA, where it is now being reviewed by OGC.
- Version 1 of the tracking system is completed. OSB received positive feedback from users. Contract money was spent.

### **16. e-MDR**

- OSB presented the project to firms attending an AdvaMed meeting and the firms were enthusiastic. OSB’s strategy includes working with the biggest firms first because they have the most expertise and submit most MDR reports.
- A contract was awarded to begin development of an IT system and will start in the fourth quarter.
- OSB needs to determine e-MDR changes needed because of upcoming changes in FDA’s Medwatch form;
- OSB needs to confirm what can be accomplished with current funding and providing timelines for expenditures.

## **OSEL**

### **17. Beowulf Cluster Research Network (COMPLETED)**

### **18. Science Infrastructure Priorities**

#### **Update**

- OSEL spent \$287K of \$1.5M. Allocating funds for this project was delayed by UFMS.
- OSEL identified additional equipment needs for White Oak, which FDA may fund.

## **OMO**

### **19. (OITCDRH) Cyclical replacement of PC/lap-tops**

- The PC replacement order was completed in May. Offices will designate who will get the new PCs.
- The procurement was delayed and the new PCs are expected to arrive in early August, and be installed in the fourth quarter.
- Stu Carlow and Paul Fisher need to determine if CDRH can save money during installation of these computers.

**20. (OITCDRH) IT Contract Support**

- Stu Carlow and Paul Fisher explained that IT contractors schedules have been resolved to avoid delays. This addresses problems they reported earlier.